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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,064	11/06/2001	Martha A. Wild	SY01106KQB	1051

24265 7590 10/22/2002

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/22/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,064

Applicant(s)

WILD ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-43 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1648

DETAILED ACTION

Notice

1. The Art Unit and Examiner handling your Application (Serial 09/994,064, Attorney Docket SY 01106 KQB US) have changed. The case has been redocketed to Examiner Zachariah Lucas of Art Unit 1648. The processing of future communications regarding this application may be facilitated by redirecting the papers accordingly.

Election/Restrictions

2. Applicant's election without traverse of Group V in Paper No. 7 is acknowledged.

3. Claims 1-38, and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Information Disclosure Statement

4. The information disclosure statement filed February 15, 2002 indicates, in accordance with 37 CFR 1.98(a)(2), that copies of the references cited in the IDS may be found in the three parent applications to the present application. However, the examiner was unable to locate copies of the following references in the indicated files, and would appreciate the applicants' assistance in expediting prosecution by providing copies of the missing references. The missing references are as follows:

a. The document listed as reference BE, Barker et al.,

Art Unit: 1648

- b. The document listed as reference BF, Cantello et al.,
- c. The document listed as reference BG, Colle et al.,
- d. The document listed as reference CJ, Nazarian et al.,
- e. The document listed as reference CM, Purves et al.,
- f. The document listed as reference CP, Ross et al.,
- g. The document listed as reference CQ, Ross et al.,
- h. The document listed as reference CT, Sanchez-Martinez et al.,
- i. The document listed as reference CU, Schnitzlein et al., and
- j. The document listed as reference DA, Weber et al.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39-43, and 45-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding an infectious laryngotracheitis virus (ILTV) glycoprotein D (gD) wherein the gD has the sequence disclosed as SEQ ID NO: 11 in the application, does not reasonably provide enablement for nucleic acids that encode any ILTV gDs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims read on an isolated nucleic acid molecule that encodes "an" ILTV gD. See e.g., claim 39. However, the application has disclosed only a

Art Unit: 1648

single ILTV gD sequence. For example, Johnson and Tyack (Vet. Microbiol., 46:221-231) discloses a sequence for an ILTV glycoprotein D that has a different amino acid sequence from the sequence disclosed in the present application. Pp.225-226. One in the art who had read the present application would not have been taught, or provided any guidance, that would have lead them to a nucleic acid encoding for the protein disclosed in Johnson and Tyack. See also, Leib et al, Avian diseases, Vol. 30, 835-837 (indicating that ILTVs from different geographic areas have some variance in restriction endonuclease patters, thereby indicating some variance in the sequences of the proteins and genes of the virus). Thus, the applicant has not provided sufficient disclosure to enable claims to any nucleic acid encoding for any ILTV gD.

7. Claim39-43, and 45-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are described above. They are rejected because, while the applicant has provided adequate written description for nucleic acids encoding for ILTV gD proteins with the sequence of SEQ ID NO: 11 in the application, there is no description for any nucleic acids encoding a ILTV gD protein that does not share the same sequence. See e.g., Johnson and Tyack; and Leib, supra. Because the applicant has provided no written description for any ILTV other than the protein of SEQ ID NO: 11, there is not sufficient written description to support the claim that read on any nucleic acid encoding any ILTV gD.

Art Unit: 1648

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on a nucleic acid molecule that encodes for an ILTV gD wherein that nucleic acid molecule is a cDNA. This claim is not enabled because the complimentary strand of DNA does not encode the protein of the gene it compliments. A nucleic acid cannot both encode a protein and be a complement to the gene encoding it. It is therefore unclear what the applicant is claiming.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 1648

10. Claims 39, 40, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Leib et al. (Avian Diseases, 30:835-837). These claims read on an isolated nucleic acid molecules that encode for an infectious laryngotracheitis virus (ILTV) glycoprotein D (gD). Leib teaches the extraction of ITLV DNA for the purposes of running endonuclease restriction mapping of the genomes. In the process, the ILTV are used to infect cells, which are then lysed. The DNA is then isolated from the lysate. As these DNAs are the ITLV genome, they inherently contain DNA encoding the ITLV gD. As the claims do not exclude DNAs that include other ITLV genes, the extracted DNA disclosed in Leib anticipates the claimed nucleic acids.

11. Claims 39, 40, 43, 45, 46, 48, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,123,949, issued to Cochran and Junker. These claims read on an isolated nucleic acid molecules that encode for an infectious laryngotracheitis virus (ILTV) glycoprotein D (gD), and to compositions of matter comprising the nucleic acid. The patent above teaches a recombinant fowlpox virus that has been engineered to contain such a nucleic acid. The patent teaches as SEQ ID NO: 19 the claimed nucleic acid. Further, it also teaches the ILTV gD gene was fused to a promoter such that the promoter would allow for expression of the gene. Patent, col. 2, lines 51-54, and col. 12, lines 33-40. Thus, the patent teaches the subject matter of the identified claims.

The patent further describes methods by which it isolated the DNA. The patent described a process of cDNA cloning. Cols. 7-9. In this process, once the DNA had been cloned, it was inserted into cells. Col. 8, lines 58-66. Further, the patent also teaches methods by which the recombinant virus were screened for the expression of the foreign genes, including ILTV gD.

Art Unit: 1648

This method comprised infecting cells with the recombinant virus. Col. 10, lines 24-45. Thus, the patent teaches, or at least renders obvious, two sets of host cells comprising DNA encoding for ILTV gD.

12. Claims 39, 40, 43, 45- 47, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,928,648, issued to Cochran. The claims are described above. The patent teaches the making of recombinant Herpesvirus for Turkeys, including embodiments wherein the gene inserted into the virus encodes ILTV gD. Col. 43, lines 49-62. This virus is made by the insertion of a DNA vector comprising the claimed nucleic acid. Col. 23, lines 34-50. The patent also discloses that the gene sequences to be inserted into the viral DNA are controlled by promoters (regulatory sequences). Col. 10, lines 41-63. The patent also discloses host cells infected by the virus, thereby comprising the DNA encoding the ILTV gD. Cols. 11-12. The patent therefore anticipates the identified claims as the patent claims priority to the applications likewise containing the above disclosures.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,123,949, issued to Cochran and Junker. For the purposes of this rejection, claim 41 is

Art Unit: 1648

being interpreted to read on a DNA complimentary to the DNA encoding for ILTV gD. Claim 42 reads on an RNA derived from the nucleic acid encoding for the ILTV gD. These claims are rendered obvious by the disclosure in the patent of the nucleic acid encoding for gD. This is because both the complimentary strand and the RNA are obvious from the DNA sequence of the gene. One of ordinary skill in the art would be motivated to make the complimentary DNA for use in probes or in PCR, while the RNA would be used for the production of the encoded protein.

Conclusion

15. The following prior art references are of record and are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.


U.S. Patent 5,252,717, and Zelnick et al., J. Gen. Virol. 74:2151-2162, and the Petrovskis et al. reference cited in the IDS of February 15, 2002 cumulatively indicate the although there are differences in the sequences among the various herpesvirus, they each seem to comprise of proteins and genes that perform similar functions and share some level of homology. The patent and the Petrovskis each indicate that the glycoprotein D homologues of the various viruses perform like functions and are antigenic. The patent teaches DNA encoding both gI and gD, and that these two proteins are antigenic. The references would be relevant to claims of the application had there also been prior art teaching both the gD and gI proteins of ILTV, whether together or individually. If these proteins had both been known, then these references would have indicated their use as antigens, and provided motivation for the combination of DNA encoding the two. Such art was not found, therefore the rejection cannot be made because there it would not be obvious to isolate or combine DNA encoding proteins where one or both were not yet known.

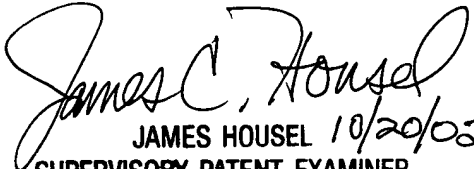
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
October 3, 2002


JAMES HOUSEL 10/20/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600